Approval Date: October 13, 2010 Revised Dates: April 10, 2013

April 11, 2012

CRITERIA FOR PRIOR AUTHORIZATION

Denosumab (Prolia®)

PROVIDER GROUP Professional

MANUAL GUIDELINES The following drug requires prior authorization:

Denosumab (Prolia)

CRITERIA FOR OSTEOPOROSIS: (must meet all of the following)

- Patient must have a diagnosis of osteoporosis
- Patient is postmenopausal **OR** a male
- Patient must have either:
 - A history of osteoporotic fracture
 - Multiple risk factors for fracture (examples of risk factors: low BMI, chronic corticosteroid use, excessive alcohol intake, cigarette smoking, eating disorders, etc.)
 - Failed or are intolerant to at least one other available osteoporosis therapy (examples: alendronate, risedronate, ibandronate, or zoledronic acid)
- Maximum of 1 injection every 6 months

CRITERIA FOR BONE LOSS: (must meet all of the following)

- Patient is at a high risk for fractures
- Patient must have either:
 - A diagnosis of nonmetastatic prostate cancer and is receiving androgen-deprivation therapy (examples: leuprolide, goserelin, flutamide, nilutamide, or bicalutamide)
 - A diagnosis of breast cancer and is receiving adjuvant aromatase inhibitor therapy (examples: anastrozole, letrozole, or exemestane)

LENGTH OF APPROVAL 12 months

Note: All patients receiving denosumab should receive 1,000mg of calcium daily and at least 400 IU of vitamin D daily.